GTAC

Gene Therapy Advisory Committee

http://www.advisorybodies.
doh.gov.uk/genetics/gtac/

Department of Health
652C Skipton House
80 London Road
London SE1 6LH
United Kingdom

To Whom It May Concern

5 November 2004

Dear Colleague

The UK Gene Therapy Advisory Committee (GTAC) has concerns regarding the safety of some lentiviral gene therapy vectors

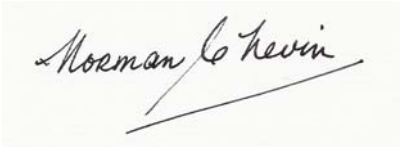
I am writing as the Chairman of the Gene Therapy Advisory Committee, the UK national supervisory body for clinical gene therapy research, to inform you of certain matters regarding some lentiviral vectors.

As part of GTAC's horizon scanning activity, reports have been received of the development of liver tumours in a pre-clinical study using lentiviral vectors. Most of the tumours occurred in a group of mice that had been treated *in utero* with a vector carrying the factor IX gene, although a small number of tumours were also observed in animals that had been treated neonatally or had received vectors carrying only marker genes. Experiments are ongoing to investigate the precise nature of the tumours and the mechanism of induction. Although the number of mice involved is small and the wider implications are not yet clear, GTAC considers that the gene therapy community should be alerted to these observations in case these have a bearing on pre-clinical screening or clinical studies that are planned or in progress outside the UK. These observations do not appear to affect any current or previous UK trials.

GTAC is keeping the current situation under review and hopes that relevant results will be published shortly. If substantial new information becomes available which concerns the gene therapy community, GTAC will issue advice as appropriate.

Should you have any further questions or concerns, please write to the GTAC Secretariat at *gtac@dh.gsi.gov.uk*.

Yours Sincerely,



PROFESSOR NORMAN C NEVIN, OBE
GTAC CHAIRMAN